IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION AT LAFAYETTE

CAROLYN G. KOCHERT, M.D.	)
Plaintiff,	)
vs.	)
ADAGEN MEDICAL INTERNATIONAL, INC.	)
a Georgia Corporation,	)
and	)
NORTH AMERICAN MEDICAL CORPORATION	)
a Georgia Corporation,	)
Defendants.	)

4:05CV0040AS

Case No.

COMPLAINT

Carolyn Kochert, M.D. ("Dr. Kochert") by and through her attorneys, Miles J. Zaremski and Alon Stein of the law firm of Kamensky Rubinstein Hochman & Delott LLP, and Randall Vonderheide of Vonderheide & Knecht, for her Complaint against defendants Adagen Medical International, Inc., a Georgia Corporation ("AMI") and North American Medical Corporation, a Georgia Corporation, ("NAM"), states as follows.

JURISDICTION AND VENUE

1. Jurisdiction is based upon 28 U.S.C. §1332 in that this is a civil action between citizens of different states and the amount in controversy exceeds the sum of $75,000, exclusive of interest and costs.

2. Venue is based upon 28 U.S.C. § 1391 (a) in that Kochert is a resident of the Northern District of Indiana, Hammond Division, and a substantial part of the events giving rise to the claims herein arose in said District and Division.

THE PARTIES

3. Dr. Kochert is a citizen of Indiana residing in Lafayette, Indiana. Dr. Kochert is a board-certified anesthesiologist and pain specialist who provides pain management services as a member of Unity Healthcare, LLC, based in Lafayette, Indiana.

4. AMI is a corporation organized and existing under the laws of the State of Georgia. Its principal place of business is located at 121 Luckie Street, Suite 200, Atlanta, Georgia 30303. Its registered agent is Terence A. Harvey, who is located at AMI's principal place of business.

5. On its website, AMI represents itself as "a full service medical consulting firm that develops and implements business growth strategies and operation plans for physicians . . . to empower their organizations to achieve a sustainable business advantage." At all times relevant to this case, AMI has acted as an authorized sales and marketing agent for NAM, manufacturer and installer of the Accu-Spinal System.

6. NAM is a corporation organized and existing under the laws of the State of Georgia. Its principal place of business is located at 1649 Sands Place, S.E., Marietta, Georgia 30067. NAM manufactures and installs the SPINA System product line (the "System") that administers Inververtebral Differential Dynamics therapy ("IDD"), a non-surgical non-invasive computer-directed treatment for back pain. It also is responsible for training physicians and their staff in the use of the System. The devices are marketed only through authorized distributors, such as AMI. NAM's registered agent is Carlos Becerra, 940 Edgewater Court, Atlanta, Georgia 30329.

FACTS

7. On or about August 16, 2000, NAM's President and CEO, Carlos Becerra, submitted to the Food and Drug Administration ("FDA") a revised 501(k) Notification of Intent to Market the Accu-Spina System (the "Notification") including Section VII that described the safety and effectiveness of the System. The Notification described the System as follows:

> i. "It consists of a tilt bed which is split into two cushions, and a controller unit. The patient is anchored by means of a pelvic harness to the traction connector for a prescribed treatment time."
> ii. " . . .intended to provide a program of treatments for relief from pain and disability for those patients suffering from low back pain. A treatment will consist of a physician prescribing a treatment period on the Spina System, and is designed to provide static, intermittent, and cycling distraction forces to relieve pressures on structures that may be causing low back pain . . .associated with herniated discs, degenerative disc disease, posterior facet syndrome, and sciatica."
> iii. "It achieves these affects through decompression of inter-vertebral discs, that is, unloading due to distraction and positioning."
> iv. "The Spina System is substantially equivalent to it's [sic] predicate devices because of the similarity in materials, design, and intended use . . [to] . . (1)The VAX-D; (2) the DRS."

A copy of Section VII is attached hereto as Exhibit "A" and is incorporated herein by this reference.

8. On information and belief, the intended purpose of IDD therapy is to mimic physical therapy by moving patients into different body positions while eliciting varied levels of back manipulation by the computer-programmed application of three different waveforms.

9. On or about August 25, 2000, Dr. Celia Witten ("Dr. Witten"), Director of the Division of General, Restorative and Neurological Devices of the Office of Device Evaluation of the Center for Devices and Radiological Health of the FDA, sent a letter (the "Witten letter") permitting NAM to begin marketing its System after a determination that the System was substantially equivalent to earlier devices (i.e., the VAX-D) that had been approved by the Division. A copy of the letter from Dr. Witten is attached hereto as Exhibit "B" and is

incorporated herein by this reference. Dr. Kochert was never shown the document nor told of its contents at any time prior to her purchase of the Accu-Spina System.

10. Prior to ordering the System, Dr. Kochert received from James Martellini ("Martellini"), an authorized AMI sales representative, a signed document dated May 28, 2003, introducing the IDD protocols and warranting that IDD therapy as delivered by the System was reimbursable through Medicare and private insurers. A copy of this document is attached hereto as Exhibit "C" and is incorporated herein by this reference.

11. This same document from Martinelli represented to Dr. Kochert that AMI's "comprehensive marketing initiative offers a purposeful strategy to generate at least 12 new IDD Therapy patients per month. With a minimum of 144 patients for the year, you will recognize a yearly A/R increase of over $400,000 as a new *passive* revenue source." (emphasis in original).

12. Dr Kochert was expressly told by Martinelli that she should bill Medicare for IDD therapy using CPT codes 97110, 97112, and 97140. She was informed by Martinelli that there would be a telephone conference regarding reimbursement procedures, but this never occurred.

13. Relying on the veracity of these representations from Martinelli, Dr. Kochert signed a Purchase and Sale Agreement with AMI ("Agreement with AMI") on or about June 2, 2003 to accept delivery of the System to provide IDD therapy to her patients who had low back pain. The total sale cost was $125,000 plus $4,800 for an extended warranty. Dr. Kochert also entered into a Finance Lease (the "Lease") with DVI Financial Services, Inc. ("DVI") on or about June 19, 2003, to finance the purchase of the System over sixty (60) months at a total cost including financing charges and warranty $165,846.60 over sixty months. Copies of the Agreement with AMI and the Lease with DVI are attached as Exhibits "D" and "E" respectively and are incorporated herein by this reference.

14. Martinelli told Dr. Kochert that the following CPT codes that had been used successfully for Medicare reimbursement for IDD therapy by other providers:

a. Code 97112 applies to "neuromuscular reeducation of movement, balance, and posture for sitting and /or standing activities";

b. Code 97140 applies only to manual therapy services and so was inappropriate to use to bill for IDD therapy that was delivered by means of a machine; and

c. Code 97110 applies to therapeutic procedures for range of motion, strength and endurance, and so was not appropriate for IDD therapy.

d. All of the above codes covered treatment intervals of a maximum of fifteen minutes per spinal region. Dr. Kochert had been trained by AMI to treat each region for a longer time interval.

15. On or about July 17, 2003, Autumn Wesson ("Wesson"), an AMI employee, instructed Dr. Kochert to use CPT codes 97110, 97112, and 97530 when billing for IDD provided to patients covered by Indiana Workmen's Compensation insurance, and Wesson provided reimbursement figures for 80% of the usual and customary charges. However, CPT code 97530 applies only to one on one therapy administered by a provider and requires constant attendance, and so was not appropriate for therapy that employed a machine. The letter from Wesson is attached hereto as Exhibit "F" and is incorporated herein by this reference.

16. On or about December 3, 2004, Dr. Kochert received a letter from Gidgette Rubin ("Rubin"), NAM Vice President Corporate Affairs, informing her that "the North American Medical team is working aggressively behind the scenes to establish stronger billing and reimbursement levels for all IDD Therapy providers. . . [w]e are in the process of retaining lobby

professionals with Medicare experience." The letter from Rubin is attached hereto as Exhibit "G" and is incorporated herein by this reference.

17. On or about March 15, 2003, Dr Kochert received a request from the Center for Medicare Services ("CMS") to provide additional documentation regarding her submitted claims for IDD therapy services. She was informed at that time that her claims for services with CPT codes 97110, 97112, and 97140 had higher than expected utilization, indicating "possible improper use" or "overutilization." A copy of this CMS request is attached hereto as Exhibit "H" and is incorporated herein by reference.

18. On or about May 3, 2004, Dr. Kochert received a letter from CMS informing her that Medicare reimbursement for IDD therapy had been wrongly paid to her by AdminiStar Federal ("AdminiStar"), the Medicare intermediary for her region. CMS stated that codes 97110, 97112, and 97140 had been subject to audit because they had been overutilized by Dr. Kochert in billing for the IDD procedures she had performed. Four hundred claims covering two hundred fifty two (252) IDD services had been reviewed by CMS and all had been disallowed. Furthermore, the letter warned that further review was ongoing and would be expanded. Attached to the letter was a summary indicating that IDD "[s]ervice is investigational and is not covered." Furthermore, the letter stated that Dr. Kochert "had or should have had knowledge that the service(s) were not medically necessary and reasonable" and therefore her obligation to repay would not be not waived. This May 3, 2004, letter is attached hereto as Exhibit "I" and is incorporated herein by this reference.

19. On or about October 27, 2004, Dr Kochert was informed by the Federal Payment Corrections Unit that she owed $8,803.20 as reimbursement for IDD overpayments and penalties. The next month, she was informed she owed an additional $17,268.24 for

overpayments. These letters from the Federal Payment Corrections Unit are attached hereto as Exhibit "J" and are incorporated herein by this reference.

20. A CMS National Coverage Decision ("NCD") had been adopted on April 15, 1997, stating that "VAX-D is not covered by Medicare," because there was insufficient scientific data to support the benefits of the technique. Later NCD updates reaffirmed this decision. The VAX-D is the predicate model on which the FDA's 501(k) approval for marketing of the System was based. Dr. Kochert had no knowledge of this decision, and AMI did not disclose this NCD to Dr. Kochert. A copy of this NCD is attached hereto as Exhibit "K" and is incorporated herein by this reference.

21. Dr. Kochert requested an in-person appeal hearing at AdminiStar that was held on or about January 4, 2005, and the Medicare Part B Hearing Officer's Decision (the "Decision") was rendered on January 11, 2005. The hearing officer again found that reimbursement for the IDD therapy services that Kochert performed should not have been allowed since IDD is investigational therapy, regardless of the type of equipment used, and there is "insufficient scientific data to support the efficacy of this technique." A copy of the Decision is attached hereto as Exhibit "L" and is incorporated herein by this reference.

22. At the January 4, 2005 hearing, Mark Sullivan ("Sullivan"), an attorney retained by NAM to assist its lobbying efforts with insurance carriers, told Dr. Kochert that Medicare had provided reimbursement for IDD therapy delivered by the System in other states, claiming that the System was dissimilar enough from the disallowed VAX-D machine to be approved for Medicare reimbursement.

23. Sullivan failed to provide this information relating to reimbursement

outside Indiana, despite repeated requests for such information by mail and phone by Dr. Kochert and her attorney.

24. In a letter to Dr. Kochert dated January 26, 2005, Sullivan stated that he did not possess any documentation pertaining to reimbursement made by CMS to other physicians for IDD therapy. A copy of Sullivan's January 26, 2005 letter is attached as hereto as Exhibit "M" and is herein incorporated by reference.

25. Private carriers have issued policies denying coverage for IDD therapy administered on the VAX-D machine, following Medicare's lead:

a. An Aetna Clinical Policy Bulletin No. 0180 dated May 11, 2004, labeled VAX-D therapy "experimental and investigational," with inadequate scientific evidence to that vertebral axial decompression therapy is an effective adjunct to conservative therapies of back surgery.

b. Blue Cross Blue Shield of Georgia issued a policy dated March 18, 1999 stating that VAX-D and the therapeutic table had not been shown to be equivalent or superior to current therapies for low back pain and so was considered "investigational/not medically necessary" for the treatment of low back pain.

Copies of these policies are attached hereto as Exhibit "N" and are incorporated herein by this reference.

26. Blue Cross Blue Shield of Illinois ("BCBSI") has issued letters to practitioners stating that IDD therapy is investigational and therefore excluded from BCBSI benefits. BCBSI further advised that an appropriate CPT for the procedure is S9090, a code that is used for non-covered procedures, and that the use of other CPT codes would result in claims being reimbursed

incorrectly and could result in audit of the claims submitted. An example of such a letter is attached hereto as Exhibit "O" and is incorporated herein by this reference.

COUNT I
COMMON LAW FRAUD BY INDUCEMENT

27. Dr. Kochert incorporates and realleges paragraphs 1-26 of this Complaint as and for paragraph 27 of Count I.

28. By virtue of the foregoing, prior to the date that Dr. Kochert entered into the Agreement with AMI, AMI made false statements of existing material fact that IDD therapy is a procedure reimbursed by Medicare and private insurance.

29. AMI made such false statements of material facts with knowledge or with reckless ignorance of their falsity to induce Dr. Kochert to purchase the System. AMI and NAM knew or were reckless in not knowing that when Dr Kochert submitted claims to Medicare for payment for IDD, such claims would be denied.

30. At all times, AMI was acting as an authorized distributor and agent for its principal, NAM.

31. NAM obtained the benefits of the representations made by its agent, AMI, to Kochert.

32. Dr. Kochert reasonably relied on the representations of AMI's authorized agents that she would receive reimbursement from Medicare and other private carriers for the IDD therapy provided by her to her patients on the Accu-Spina System.

33. As proximate cause of the aforementioned misrepresentations, Dr. Kochert has been injured, and will continue to suffer financial losses in the form of extra repayments to Medicare and to private insurance carriers on an ongoing basis or losses in the form of revenues

anticipated to be earned and collected from and on behalf of patients provided treatment with the Accu-Spina System as a result of payments from Medicare/private insurance.

34. The foregoing actions were wanton and willful.

WHEREFORE, Dr. Kochert prays for judgment in her favor and against AMI and NAM and for an order awarding Dr. Kochert damages in an amount to be determined at trial, plus costs, punitive damages, consequential damages, and for such other and further relief as this Court deems just and appropriate.

Dated: June 20, 2005

Respectfully submitted,

CAROLYN G. KOCHERT, M.D.

By: _____
Miles J. Zaremski

By: _____
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